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(54) **MEDICAL DEVICE AND PROCEDURE SIMULATION**

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(57) **ABSTRACT**

A device is disclosed that includes an interface member including a material and a manipulandum movable in a degree of freedom. The manipulandum is able to penetrate the material. A sensor is configured to output a position signal based on the position of the manipulandum. An actuator is configured to output haptic feedback by applying a compressive force to the material based on the position signal. In other embodiments, a method is disclosed that includes receiving a position signal associated with a position of a manipulandum, where at least a portion of the manipulandum penetrates the interface material. Haptic feedback is output by varying a density of the interface material based on the position signal.

22 Claims, 6 Drawing Sheets
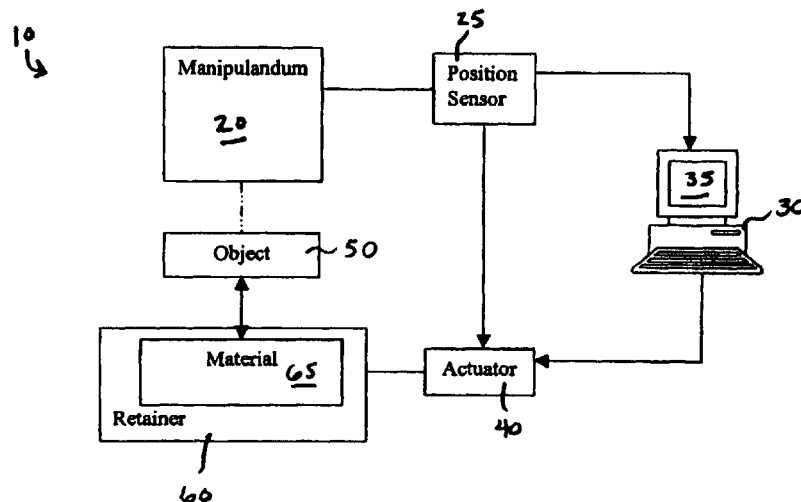
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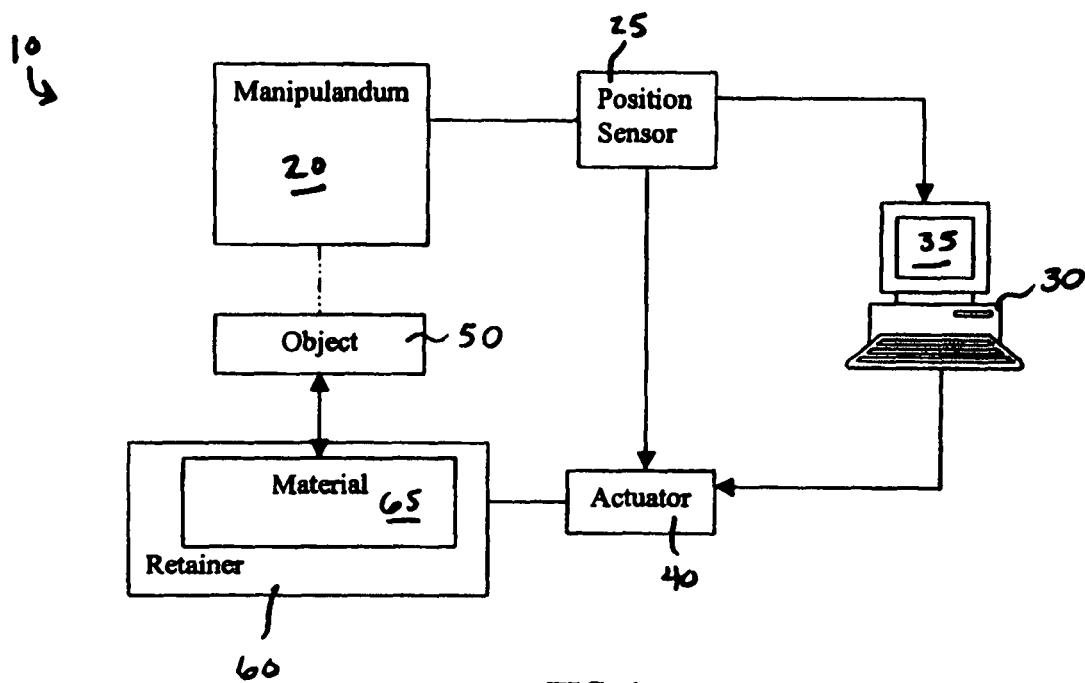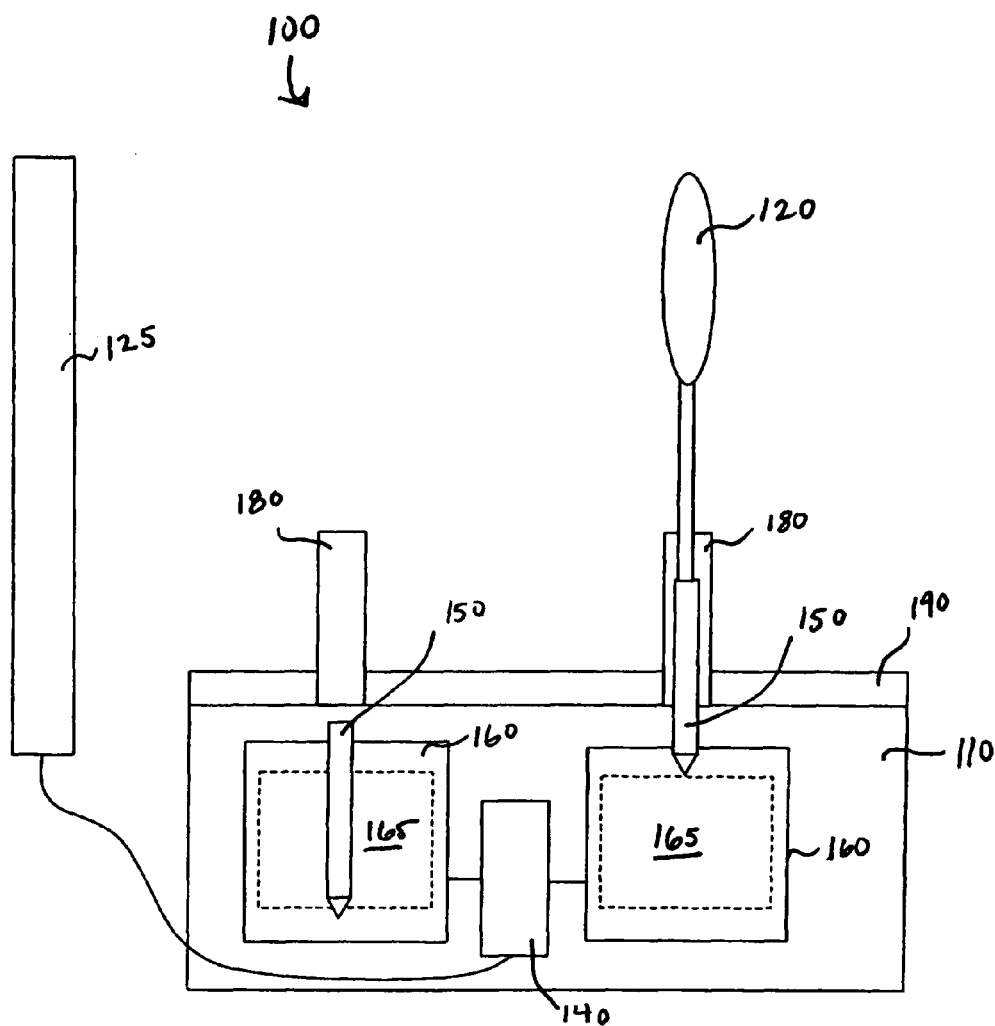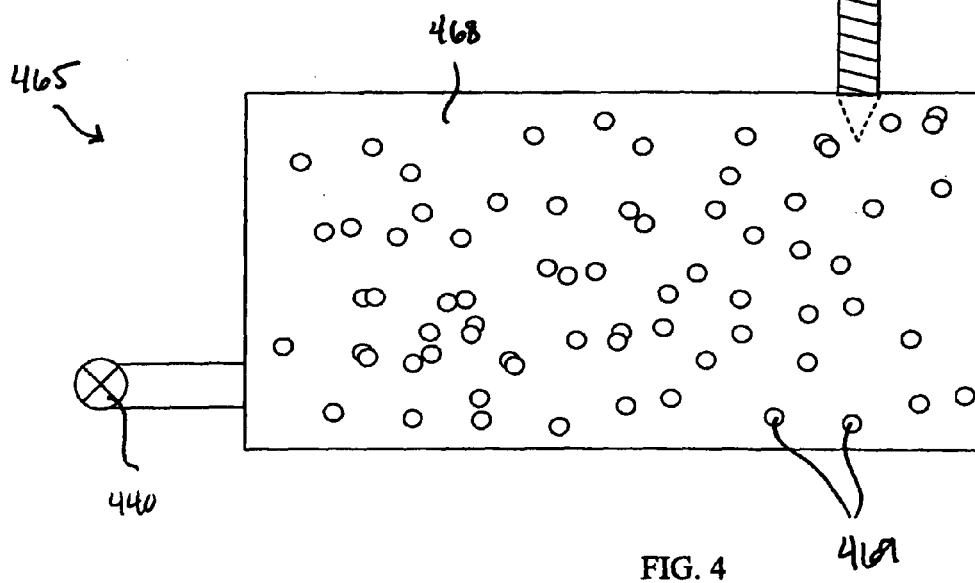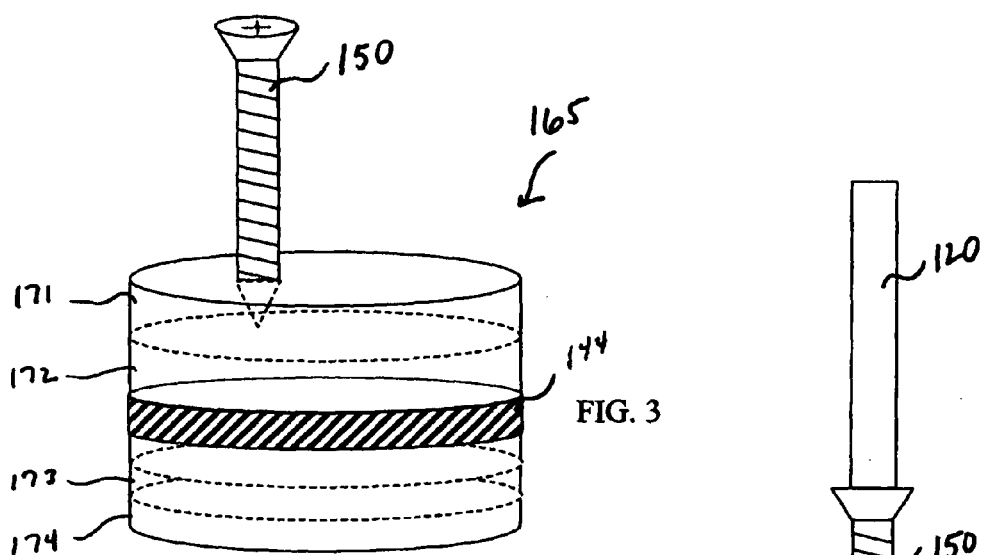
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FIG. 1

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FIG. 2

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FIG. 3

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FIG. 4
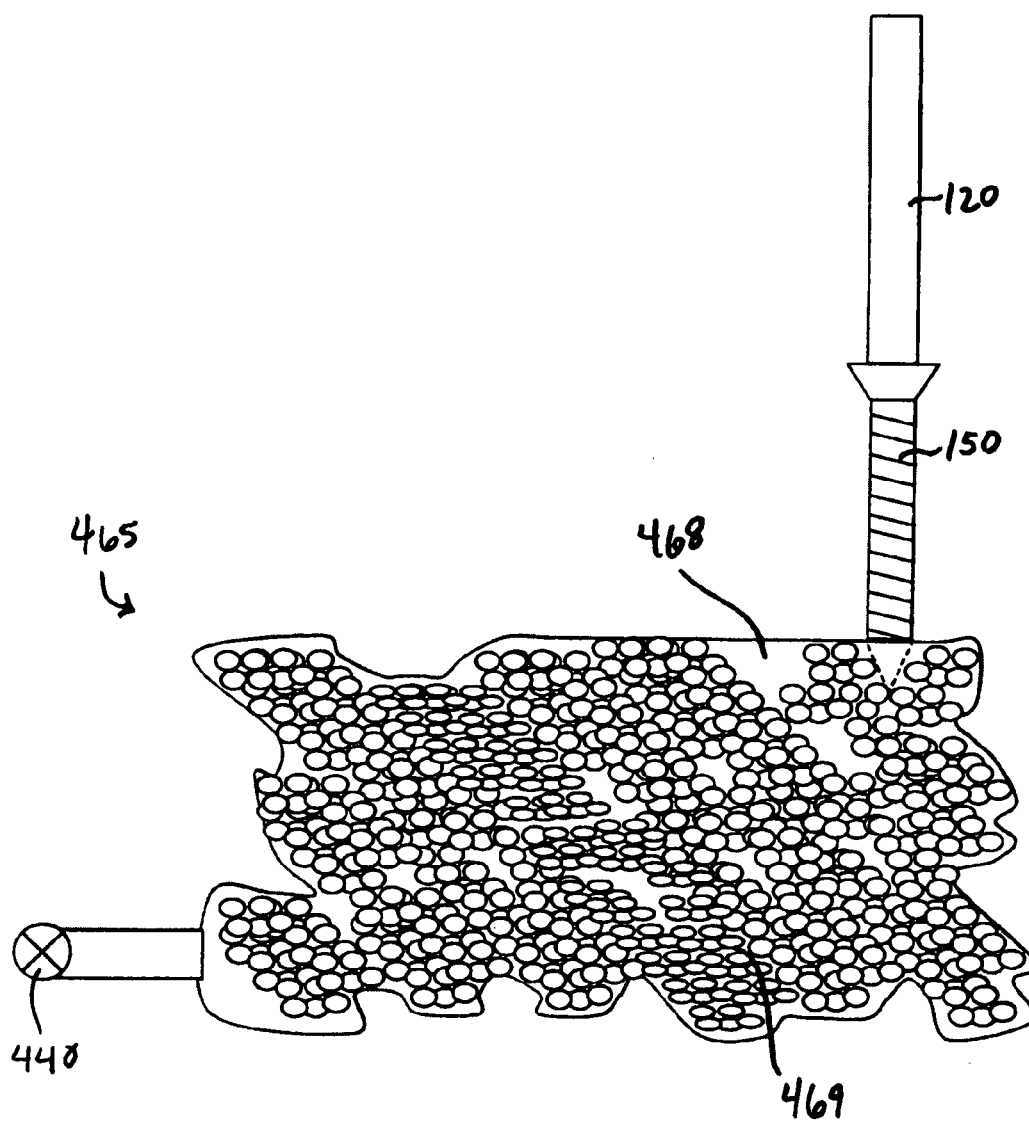
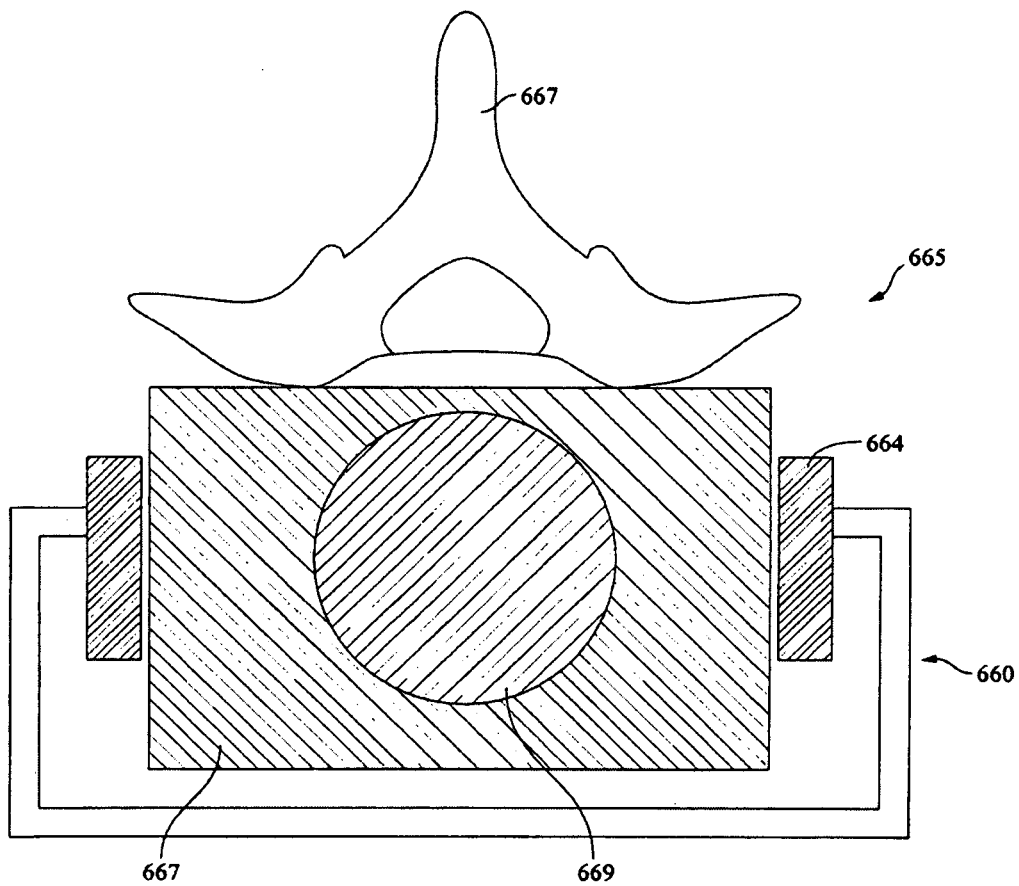FIG. 5

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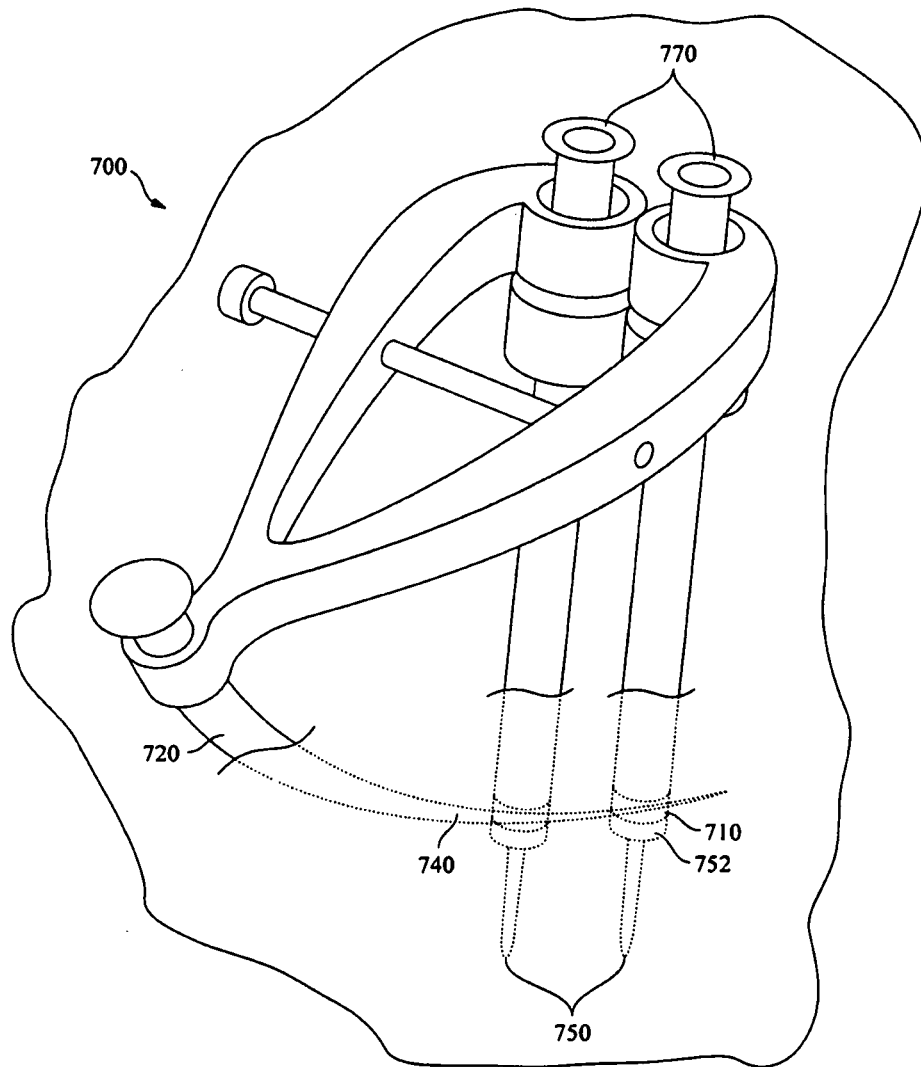667   669

FIG. 6

FIG. 7

MEDICAL DEVICE AND PROCEDURE SIMULATION

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application is a continuation of co-pending U.S. patent application Ser. No. 10/803,080 filed Mar. 18, 2004, in the name of inventors Richard L. Cunningham and Robert Cohen and entitled "Medical Device and Procedure Simulation", commonly owned herewith.

BACKGROUND

The invention relates generally to medical procedure simulations, and more particularly to a method and apparatus for simulating a spinal stabilization procedure.

Minimally invasive medical procedures reduce danger to patients, decrease recovery time, and provide superior outcomes when compared to open surgery. The physician typically operates at a distance from the surgical site, however, frequently using remote cameras or other imaging modalities, and remotely controlled surgical tools. Consequently, these procedures can be difficult to master. Thus, the use of procedure simulation systems provides a learning environment in which the physician can gain needed skills without putting patients at risk.

A known minimally invasive spinal stabilization procedure uses four screws and two connecting rods to stabilize two adjacent vertebrae. The procedure makes six puncture incisions; one each for the four screws and the two connecting rods. After two screws are inserted in adjacent vertebrae, they are connected with a curved rod and the procedure is repeated with two more screws. The connecting rod is aligned with slots in two screws by means of a device that constrains the curved rod to move in an arc that is constrained to properly align the two screws, which are in turn each attached to two legs of the alignment device.

Known medical procedure simulators have been developed that simulate the functionality of open spinal procedures. In one example of such simulators, a user manipulates various devices in connection with simulated bone structure. The bone structure is simulated with castings fabricated from a material such as compressed sawdust. Minimally invasive procedures, however, use fluoroscopic guidance systems. A simulator using such technology would be expensive to produce and would needlessly expose the user to radiation. Additionally, using known physical model simulation techniques would not allow the simulation of certain features such as physical anatomical variations (e.g., varying bone densities), vital signs and other important aspects of the procedure.

Thus, a need exists for a medical procedure simulation device and method that can combine physical models with computer controlled feedback, simulated fluoroscopy, and simulated physical anatomical variations to enable the user to experience a more realistic training experience.

Overview

A device is disclosed that includes an interface member including a material and a manipulandum movable in a degree of freedom. The manipulandum is able to penetrate the material of the interface member. A sensor is configured to output a position signal based on the position of the manipulandum. An actuator is configured to output haptic feedback by applying a compressive force to the material based on the position signal.

In other embodiments, a method is disclosed that includes receiving a position signal associated with a position of a manipulandum, where at least a portion of the manipulandum penetrates the interface material. Haptic feedback is output by varying a density of the interface material based on the position signal.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic representation of a medical procedure simulation device according to an embodiment.

FIG. 2 is a block diagram of a device according to an embodiment.

FIG. 3 is a perspective view of an interface member for use with the device illustrated in FIG. 2.

FIG. 4 is a plan view of an interface member for use with the device according to an alternative embodiment under a first set of conditions.

FIG. 5 is a plan view of the interface member illustrated in FIG. 3 under a second set of conditions.

FIG. 6 is a cross-sectional view of a device according to another embodiment.

FIG. 7 is a perspective view of an example of a medical device that can be simulated by embodiments.

DETAILED DESCRIPTION

Devices and methods for simulating medical procedures are described. More specifically, a particular medical device for minimally invasive spinal stabilization and an associated procedure is described and then a simulation device and method for this medical device and procedure is described. The Medtronic Sofamor Danek CD HORIZON® SEXTANT™ Percutaneous Rod Insertion Set 700, illustrated in FIG. 7, uses CD HORIZON® M8 cannulated titanium Multi-Axial Screws 750. Cannulated screws 750 are used to facilitate percutaneous navigation of the pedicles of a vertebrae with a guide wire (not shown). A series of tubular dilators 770 are used to create a tunnel through the soft-tissues of the back, prior to placement of the screws 750 over the guide wire. The cannulated screws 750 are comparable in strength, profile, and fatigue resistance to the CD Horizon M8 multi-axial screws that are well known to spine surgeons. The screws vary in length from 35 to 55 mm long.

The rods 740 that are used to connect the pedicle screws are pre-cut and pre-bent in 5 mm increments for single level cases, and in 1 cm increments for bi-level cases. The pre-contoured rods range in size from 30 to 90 mm in length. The rods 740 are pre-contoured because the insertion technique depends upon a precise geometric arrangement of the screw heads 752 that are then matched to the radius of curvature of the rod 740.

Each cannulated screw 750 is fitted with a specially designed screw extender 710 that allows the multi-axial heads to be manipulated independently. This extender 710 also has an integrated mechanism (not shown) for holding, engaging, and securing the setscrew (not shown) that fixes the rod 740 to the screw head 752.

After the pedicle screws 750 have been inserted into the proper vertebral bodies (not shown) and their positions have been confirmed radiographically, the heads 752 of the pedicle screws 750 are connected to each other with rod 740. The screw heads 752 can be percutaneously manipulated with the screw extenders 710, and smooth rod insertion is made possible by connecting the two screw extenders 710 together, which assures that the multi-axial screw heads 752 are aligned along the same curvilinear path as the pre-contoured

rod **740**. The geometry of the screw extenders **710** and rod introducer **720** dictates that the rod **740** follows a precise path, through the soft tissues and into properly aligned screw heads **752**.

Proper torque on the setscrews (not shown) that secure the rod **740** to the pedicle screws **750** is assured with a "break-off" mechanism that snaps off the screw head when the proper torque has been reached. After the pedicle screw **750** and rod **740** construct has been assembled and confirmed with the fluoroscope, the setscrews are secured and torqued with the "break-off" mechanism. The device **700** can be simulated using embodiments of the invention as described below.

FIG. **1** is a schematic representation of a medical procedure simulation device **10** according to an embodiment of the invention. The device **10** includes a manipulandum **20** that is coupled to a position sensor **25** and is movable in at least two degrees of freedom. The position sensor **25** is configured to output signals to an actuator **40** based on the position of the manipulandum **20**. An object **50** is removably or fixedly coupled to the manipulandum **20**. The actuator **40** is coupled to a retainer **60**. The retainer **60** houses an interface member **65** including a material that is configured to receive the object **50**. The actuator **40** is configured to engage the retainer **60** in such a manner as to modify the density of the material of interface member **65** based on the position of the manipulandum **20** and/or the object **50**, as will be described below.

In some embodiments of the invention, the medical procedure simulation device **10** includes a processor **30** that is configured to receive signals from the position sensor **25**, and output signals to the actuator **40** and to a display **35** that is configured to output images associated with the medical procedure simulation as described below.

The display **35** is coupled to the processor **30** and is configured to output a simulated image based on data values associated with a position of the manipulandum **20** relative to, for example, the interface member **65**. The processor **30** can be, for example, a commercially available personal computer, or a less complex computing or processing device that is dedicated to performing one or more specific tasks. For example, the processor **30** can be a terminal dedicated to providing an interactive virtual reality environment.

The processor **30**, according to one or more embodiments of the invention, can be a commercially available microprocessor. Alternatively, the processor **30** can be an application-specific integrated circuit (ASIC) or a combination of ASICs, which are designed to achieve one or more specific functions, or enable one or more specific devices or applications. In yet another embodiment, the processor **30** can be an analog or digital circuit, or a combination of multiple circuits.

The processor **30** includes a memory component (not shown in FIG. **1**). The memory component can include one or more types of memory. For example, the memory component can include a read only memory (ROM) component and a random access memory (RAM) component. The memory component can also include other types of memory that are suitable for storing data in a form retrievable by the processor **30**. For example, electronically programmable read only memory (EPROM), erasable electronically programmable read only memory (EEPROM), flash memory, as well as other suitable forms of memory can be included within the memory component. The processor **30** can also include a variety of other components, such as for example, co-processors, graphics processors, etc., depending upon the desired functionality of the medical procedure simulation device **10**.

The processor **30** is in communication with the memory component, and can store data in the memory component or retrieve data previously stored in the memory component.

The components of the processor **30** can communicate with devices external to the processor **30** by way of an input/output (I/O) component (not shown in FIG. **1**). According to one or more embodiments of the invention, the I/O component can include a variety of suitable communication interfaces. For example, the I/O component can include, for example, wired connections, such as standard serial ports, parallel ports, universal serial bus (USB) ports, S-video ports, local area network (LAN) ports, small computer system interface (SCSI) ports, and so forth. Additionally, the I/O component can include, for example, wireless connections, such as infrared ports, optical ports, Bluetooth® wireless ports, wireless LAN ports, or the like.

The processor **30** is configured to receive signals from the position sensor **25** and output signals to the actuator **40**. The processor **30** receives data values associated with the position (i.e., location and orientation) of the manipulandum **20** and, hence, the position and orientation of object **50** with respect to the interface member **65**. The position signals can be absolute position signals or can be measured as a relative distance and direction from a predetermined reference point (e.g., the interface member **65**, the retainer **60**, or a support surface on which the device **10** is positioned). In alternative embodiments, a sensor or multiple sensors (not shown) can be disposed in the object **50**, the interface member **65** or the retainer **60**, and can be configured to determine the location of the manipulandum **20**. Alternatively, the object **50**, the interface member **65**, or the retainer **60** can include a wireless or wired transmitter (not shown) that sends a position signal to the processor **30** to determine position information of the object **50** relative to the interface member **65**. In some embodiments of the invention, the sensors can detect multiple degrees of freedom of the manipulandum (e.g., translation, pitch, yaw, rotation, etc.)

As the manipulandum **20** is moved from one position to another, the images output on the display **35** are updated based on the position signal. It is desirable for the position of the object **50** relative to the interface member **65** to be coordinated in a realistic sense with respect to the images output on the display **35**. For example, when the material of the interface member **65** is a simulated pedicle of a vertebrae and the object **50** is a screw or a simulated screw, the images output on the display **35** should correspond accordingly. Images viewed on the display are obtained from actual spinal stabilization procedures and are reproduced based on position signals received from the position sensor **25**. For example, in a spinal stabilization simulation, where the screws have been properly inserted, the image displayed can show a properly simulated screw.

The medical procedure simulation device **10** is configured to output haptic feedback based on the position of the manipulandum **20**. The haptic feedback is designed to replicate the sensation that would be experienced by a user, for example, during a spinal stabilization procedure as described above. More specifically, as the user screws the object **50** into the material of the interface member **65**, haptic feedback is output based on the position and orientation of the object **50**. The position and orientation of the object **50** is related to the position and orientation of the manipulandum **20** by virtue of its coupling to the manipulandum **20**. The manipulandum **20** can be rotated about an axis defined along the length of the manipulandum **20** and translate along that same axis while rotating. Depending upon the type of manipulandum **20** that is used, the manipulandum **20** can translate along the axis while a part or all of the manipulandum **20** does not rotate.

Referring to FIG. **2**, a block diagram of a medical procedure simulation device according to an embodiment of the

invention is illustrated. The medical procedure simulation device 100 includes a housing 110 covered with a simulated skin 190. The housing 110 can be, for example, a mannequin formed as a human body. The simulated skin 190 is configured to provide the sensation of skin penetration when inserting various elements of the device 100 as described below. The simulated skin 190 is a self-healing material in that the simulated skin is penetrable, but is able to return substantially to its original form once the inserted elements of the device 100 are removed.

The housing 110 defines an opening that is configured to receive at least one interface member 165 that includes a material configured to simulate a bone structure, such as a vertebrae. The material of the interface member 165 is configured to receive an actual or simulated pedicle screw 150. The material is maintained in an interior portion of a retainer 160. In embodiments of the medical procedure simulation device 100, the interface member 165 material is fabricated from, for example, compressed sawdust such as that available from Sawbones® Worldwide in Vashon, Wash. Alternatively, the material can be fabricated from Selective Laser Sintering (SLS). SLS is a process by which three-dimensional parts are created by the fusing or sintering of powdered thermoplastic materials with the heat from an infrared laser beam. In this manner, various materials, such as compressed nylon, can be used. The material can be discarded after a single use, or may be used numerous times depending upon the durability of the material.

A screwdriver 120 is used to drive the screw 150 to penetrate the material of the interface member 165. While being manipulated, the screws 150 are firmly attached to screwdriver 120. The screwdriver 120 and the screw 150 are guided into the housing 110 through a shaft 180. The shaft 180 can be fixed in the housing 110 or can be removably coupled such that the user of the device is able to simulate proper insertion of the shaft 180 as part of the simulated procedure.

A sensor 125 is configured to output a position signal based on the position of the screwdriver 120. Because of the connection between the screwdriver 120 and the screw 150, the location and orientation of the screw 150 can be determined based on the position signal associated with the position of the screwdriver 120 and/or the position and orientation of the shaft 180. The sensor 125 can incorporate any known methods appropriate for tracking the position of the screwdriver 120. For example, the sensor may be a visual sensor configured to track marks on the screwdriver 120 or an extension (not shown) coupled to the screwdriver 120. Alternatively, a mechanical arm (not shown) can be coupled at one end to the screwdriver 120 and at another end to the position sensor 125. A mechanical arm such as the one used in the Microscribe® device available from Immersion Corporation in San Jose, Calif. is suitable for some embodiments of the invention. An example of such a mechanical arm is disclosed in U.S. patent application Ser. No. 09/687,923, now U.S. Pat. No. 6,697, 748, which is incorporated herein by reference.

The position sensor 125 is coupled to an actuator 140 and is configured to output position signals. Actuation signals based on the position signals are then sent to the actuator 140. Alternatively, if the actuator 140 has an embedded processor, the position signals are sent directly to the actuator 140. The actuator 140 is coupled to the retainer(s) 160 and is configured to output haptic feedback based on the position signal by applying a compressive force to the material of the interface member 165.

The medical simulation device 100 can be used, for example, to train users to orient the screws 150 to align properly with the pedicles of a vertebrae. In an actual proce-

dure, as the screw is successfully embedded in the vertebrae, the screw encounters varying density bone that is visible on a fluoroscope display and is perceptible to the user's sense of touch. The medical procedure simulation device 100 simulates the sensation of encountering varying bone density by varying the density of the material of the interface member 165.

Referring to FIG. 3, an example of an interface member 165 is illustrated in which the material includes multiple layers 171, 172, 173 and 174. The density of the material in layers 171, 172, 173 and 174 may be the same or different. As illustrated in FIGS. 2 and 3, the screw 150 is configured to penetrate the layers 171, 172, 173 and 174 of interface member 165. To further vary the density of the material of the interface member 165, the actuator 140 includes a clamp or band 144 that encircles the interface member 165. As discussed above, the actuator 140 is configured to vary the density of the material based on the position signal received from the position sensor 125. Although the clamp or band 144 is shown in FIG. 3 as surrounding layer 172 only, in other embodiments the claim or band 144 can surround more or all layers of the material of the interface member 165.

In use, as the screw 150 is manipulated and penetrates the material of the interface member 165, the diameter of the clamp 144, and likewise the opening defined by the clamp 144, can vary. The diameter of the clamp 144 may be varied by actuation of a motor (not shown) coupled to the clamp 144. With the varying diameter of the clamp 144, the compressive force applied to the material of the interface member 165 varies as well. Accordingly, haptic feedback is provided, thereby providing the sensation of a variable density bone structure.

The density of the material of interface member 165 can be varied to simulate various conditions. For example, if the screw 150 is not properly inserted (e.g., inserted at an improper angle) the clamp 140 will quickly loosen to simulate shearing of the bone structure. Alternatively, if the screw 150 is properly inserted, the clamp 140 will compress the material to simulate dense bone structure until the screw 150 moves an appropriate distance, at which point the clamp will release to simulate entry of the screw 150 into the less dense portion of the bone structure.

An alternative embodiment of an interface member for use with the medical simulation device 100 is illustrated in FIG. 6. The interface member 665 includes a structural member 667 that simulates various elements of the spine that could be encountered when performing various medical procedures. The material of the interface member 665 can be fabricated from varying density material. For example, a first portion 667 of the material can be fabricated using a material having a density and a second portion 669 of the material can have a density different from the density of the first portion 667. In the illustrated embodiment, the actuator 644 includes a band that is coupled to the retainer 660. Alternatively, the band is integrally formed as part of the retainer 660. The density of the first portion 667 of the material and the second portion 669 of the material can be further varied by actuation of the band based on the position signal received by the actuator 644 as described above.

An alternative embodiment of an interface member for use with the medical simulation device 100 is illustrated in FIGS. 4 and 5. FIG. 4 illustrates interface member 465 in a decompressed condition and FIG. 5 illustrates interface member 465 in a compressed condition. In the illustrated embodiment, the interface member 465 defines a chamber 468 including compressible beads 469 that can be compressed and decompressed to simulate various conditions based on the position

of the screwdriver **120**. The beads **469** can be fabricated from, for example, polystyrene, nylon (polyamide) powder, sugar, etc. FIGS. **4** and **5** are for illustrative purposes only and a greater bead density than that shown would be required to pressurize the interface member **465** to a degree sufficient to simulate bone density.

As illustrated, the density of the beads in the interface member **465** can be modified via vacuum pump **440**. When the area inside the chamber **468** is evacuated, the external air pressure causes the beads to compress. The chamber **468** contains a sufficient amount of compressible beads to pressurize the interface member **465**. As discussed above, as the screw **150** penetrates the interface member, the density can be varied to output haptic feedback based on the position of the screwdriver **120**. The chamber **468** has a seal sufficient to prevent air from leaking into or escaping from the chamber **468** at the entry point of the screw **150**.

The density of the beads **469** can be varied by modifying the size of the chamber **468**. In such an embodiment, this chamber **468** is defined by a flexible housing that collapses around the beads **469** to increase the density. Likewise, the flexible housing can be expanded to decrease the density.

CONCLUSION

While various embodiments of the invention have been described above, it should be understood that they have been presented by way of example only, and not limitation. Thus, the breadth and scope of the invention should not be limited by any of the above-described embodiments, but should be defined only in accordance with the following claims and their equivalence.

The previous description of the embodiments is provided to enable any person skilled in the art to make or use the invention. While the invention has been particularly shown and described with reference to embodiments thereof, it will be understood by those skilled in art that various changes in form and details may be made therein without departing from the spirit and scope of the invention.

For example, although the manipulandum **20** is described as being a screwdriver **120** in some embodiments of the invention, in an alternative embodiment the manipulandum can be any tool that is configured to move the object into the material of the interface member. For example, the manipulandum can be a drill, a hammer, a pneumatic hammer, a pneumatic or hydraulic press, a pneumatic or hydraulic drill or screwdriver, etc.

Although the processor **30** is described above as being directly coupled to the manipulandum **20** and the actuator **40**, in an alternative embodiment, the processor **30** can be coupled to the medical procedure simulation device **10** via a network.

Additionally, although the position sensor **125** is described above as being configured to output position signals based on the position of the screwdriver **120**, in some alternative embodiments, the position sensor is configured to track the position of the screws **150** directly. In a further alternative embodiment, sensors embedded in the interface member **165** can replace or augment the position sensor **125**.

Although the material of the interface member **165** is described above as being disposed in the retainer **160**, in some alternative embodiments, the retainer **160** need not be used. In other words, the actuator **140** can be directly coupled to the material and apply a compressive force directly to the material.

Although the medical procedure simulation device **110** is not illustrated as including the various rods and external

structures associated with the actual device illustrated in FIG. **7**, the simulation device can include any or all of the elements associated with the actual device whether illustrated or not.

Although the manipulandum **20** and object **50** are disclosed as being separate elements, the manipulandum **20** and object **50** can be fixedly coupled as discussed above and thus considered a single element. In this manner, the manipulandum can penetrate the interface member when the object is considered a part of the manipulandum.

Although the clamp **144** is illustrated as a thin band that surrounds only a portion of the interface member **165**, the clamp **144** may be wide enough to cover the entire length of the material of the interface member **165**. Moreover, while only one actuator is illustrated, the medical procedure simulation device **100** may include more than one actuator. Each actuator may be associated with a different interface member, or multiple actuators may be arranged to selectively compress a single interface member.

Although the housing **110** is disclosed above as having an opening to receive the interface members **165**, in some alternative embodiments, the interface members may be coupled directly to the simulated skin **190** and a housing **110** is not needed.

Although the interface member **465** is described as having beads **469** that are compressed by decreasing the volume of chamber **468**, in alternative embodiments, the beads **469** can be pre-compressed by means of a band placed around chamber **468**. For example, the beads **469** can be initially pressurized a predetermined amount and then either further pressurized by pressurizing the chamber as discussed above, or depressurized by expanding the chamber against the band placed around the chamber.

What is claimed is:

1. A device, comprising:

an interface member including a compressible material of selectively variable density;

a manipulandum movable in a degree of freedom, the manipulandum configured to cause an object to penetrate the material;

a sensor configured to output a position signal based on the depth of penetration of the object within the material; and

an actuator configured to:

apply a first compressive force to the material to change the density of the material within at least a portion of the interface member in response to the position signal, wherein the change in density of the material imparts a haptic effect to the manipulandum, and

apply a second compressive force to the material substantially simultaneously with the first compressive force, wherein the first compressive force is different from the second compressive force.

2. The device of claim **1**, wherein the material includes a plurality of compressible beads.

3. The device of claim **1**, wherein the material includes a plurality of polystyrene beads.

4. The device of claim **1**, wherein the interface member includes a simulated bone structure.

5. The device of claim **1**, wherein the manipulandum is rotatable about an axis defined along a length of the manipulandum when the manipulandum has penetrated the material.

6. The device of claim **1**, wherein the actuator is a clamp coupled to the interface member, the clamp configured to decrease a volume of the interface member to change the density of the material.

7. The device of claim **1**, wherein the actuator is a vacuum coupled to the interface member.

8. The device of claim **1**, the actuator being a first actuator, the device further comprising a plurality of actuators including the first actuator, each actuator from the plurality of actuators being an individually actuatable clamp.

9. The device of claim **1**, wherein the material comprises a plurality of layers, and wherein:

the actuator is further configured to apply the first compressive force to a first layer of the plurality of layers, and apply the second compressive force to a second layer of the plurality of layers.

10. A device, comprising:

a retainer defining an interior in which a compressible material is disposed and having a selectively variable density when a compressible force is applied thereto;

a manipulandum movable in a degree of freedom, the manipulandum configured to cause an object to penetrate the material;

a sensor configured to output a position signal based on the depth of penetration of the object within the material; and

an actuator coupled to the retainer, the actuator configured to:

apply a first compressible force to the material to change the density of the material in response to the position signal, wherein the change in density of the material imparts a haptic effect to the manipulandum, and

apply a second compressible force to the material substantially simultaneously with the first compressible force, wherein the first compressible force is different from the second compressible force.

11. The device of claim **10**, wherein the manipulandum includes a first portion and a second portion, the second portion configured to be removably coupled to the object.

12. The device of claim **10**, wherein the manipulandum is configured to move in a rotary degree of freedom about an axis, and move simultaneously along the axis.

13. The device of claim **10**, wherein the interface member includes a simulated pedicle of a vertebrae.

14. The device of claim **10**, wherein the interface member includes a simulated bone structure.

15. The device of claim **10**, wherein the retainer is configured to compress the material in response to actuation of the actuator.

16. The device of claim **10**, wherein the manipulandum is rotatable about an axis defined along a length of the manipulandum when the manipulandum has penetrated the material.

17. The device of claim **10**, wherein the retainer is a clamp having an opening, the actuator including a motor configured to modify a size of the opening based on the position signal.

18. The device of claim **10**, wherein the manipulandum is a screwdriver and the object is a screw.

19. The device of claim **10**, further comprising:

a guide configured to receive at least a portion of the manipulandum, the guide being removably coupled adjacent to the retainer.

20. The device of claim **10**, wherein the manipulandum is movable in two degrees of freedom.

21. The device of claim **10**, wherein the compressible material is not rigid.

22. The device of claim **10**, wherein the material comprises a plurality of layers, and wherein:

the actuator is further configured to apply the first compressive force to a first layer of the plurality of layers, and apply the second compressive force to a second layer of the plurality of layers.

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